APR 1 2 2002

Sysmex

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
The assigned 510(k) number is: K020496.

1. Submitted by:	Sysmex Corporation of America 6699 Wildlife Way Long Grove, IL 60047 Phone: (847) 726-3675 FAX: (847) 726-3559 Contact person: Nina Gamperling Date prepared: February 13, 2002
2. Name of Device:	Trade or proprietary name: HPC (Hematopoietic Progenitor Cell) parameter on the IMI Channel of the Sysmex® SE-9500 and XE-2100, Automated Hematology Analyzer. Common name: HPC parameter Classification name: HPC parameter on the IMI Channel, Automated Differential Cell Counter, Sysmex® SE-9500 and XE-2100 (21 CFR 864.5220)
3. Predicate Device:	The HPC parameter of the IMI channel on the Sysmex® SE-9500 and XE-2100 is substantially equivalent to Colony Forming Unit (CFU) and Total Nucleated Count (TNC) methods used in the United States prior to 1976.
4. Device Description:	The SE-9500 and XE-2100 have an immature myeloid information (IMI) channel, which identifies and enumerates immature cells in addition to the traditionally reported parameters of an automated cell differential. (Note: Special software/hardware is required to obtain results described.)
5. Intended Use:	The HPC (hematopoietic progenitor cell) parameter of the IMI Channel on the Sysmex® SE-950 and XE-2100 for *in Vitro* Diagnostics is used as a screen for the optimal presence of hematopoietic progenitor cells in peripheral blood and cord blood samples.
6. Substantial equivalence-similarities and differences	The following table compares the HPC parameter of the IMI Channel with predicate methods.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

Comparison Table to Predicate Methods

	Colony Forming Unit (CFU)	TNC	Flow Cytometry CD34+	HPC parameter of IMI Channel
	Predicate	**Predicate**	**Routine**	**New method**
Intended Use	To count the number of progenitor cell colonies on a growth medium plate	To screen for optimal presence of progenitor cells in stem cell harvest & cord blood samples	CD34+ is a surrogate marker to screen for optimal presence of progenitor cells in stem cell harvest & cord blood samples	To screen for optimal presence of progenitor cells in stem cell harvest & cord blood
Methodology	Real counting of progenitor cells on growth medium plates.	Total nucleated count from hematology analyzer.	Enumeration of CD34+ cells by flow cytometry.	Hematopoietic progenitor cell count from hematology analyzer
Type of Anticoagulant	Heparin	EDTA	Heparin and EDTA	EDTA
Specimen Type	Peripheral blood, apheresis product & cord blood samples	Peripheral blood, apheresis product & cord blood	Peripheral blood, apheresis product & cord blood	Peripheral blood & cord blood
Accuracy	Method of real counting of progenitor cells established as reference method.	Comparison to CFU showed good correlation.	Comparison to CFU showed good correlation.	Comparison to CFU showed good correlation.
Time Required (per sample) for method	14 days	90 seconds	2 hours	90 seconds
Cost (per sample) for method	Approximately $300	Approx $1.35	$35-$105	Approx $1.35
Quality of Technical Support	Highly specialized laboratory personnel; Run in duplicate.	Hematology laboratory personnel.	Highly specialized lab personnel; Run in duplicate.	Hematology laboratory personnel; Run in duplicate.

7. Clinical Performance Data: Studies were performed to evaluate the equivalency of the HPC parameter to the predicate devices. Results indicated equivalent performance.

8. Conclusions: The performance data demonstrated substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Nina M. Gamperling, MBA, MT (ASCP), RAC
Manager, Regulatory Affairs
Sysmex Corporation of America
6699 Wildlife Way
Long Grove, Illinois 60047-9596

APR 12 2002

Re: k020496
Trade/Device Name: Hematopoietic Progenitor Cell (HPC) parameter of the IMI Channel on the Sysmex® SE-9500™ and XE-2100™, Automated Hematology Analyzers
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: II
Product Code: GKZ
Dated: February 13, 2002
Received: February 14, 2002

Dear Ms. Gamperling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K020496

Device Name: Hematopoietic Progenitor Cell (HPC) parameter of the IMI Channel on the Sysmex® SE-9500™ and XE-2100™, Automated Hematology Analyzers

Indications For Use:

The HPC (hematopoietic progenitor cell) parameter of the IMI Channel on the Sysmex® SE-9500 and XE-2100 for *in Vitro* Diagnostics is used as a screen for the optimal presence of hematopoietic progenitor cells in peripheral blood and cord blood samples.

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K020496

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CHRD, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** ____